

REJECTION UNDER '102

Claims 27- 29 have been rejected under 35 U.S.C. '102(b) or '102(e) as being anticipated by Barnes (U.S. 4,721,723) or Ward et al. (U.S. 5,872,132). This rejection is respectfully traversed.

Applicants traverse this rejection on the grounds that the subject matter of claim 27 was patented in claims 2 and 4 of U.S. Patent 6,063,927 (Craig et al.) and thus, to the extent the U.S. Patent and Trademark office has already indicated the patentability of this kind of subject matter, it is applicants' instant earlier filed application (under §120) that is entitled to such patent protection.

Moreover, the Examiner's final rejection is premised on three (3) errors. First, the Examiner asserts that there is insufficient evidence to show that the products of Craig claims 2 and 4 are identical with the products of instant claims 27-29 since different solvents can make different, patentably distinct forms. But neither Craig claims 2 and 4 nor the instant claims 27-29 are solvent specific. The claims can not be distinguished based on solvent since neither set of claims contains a solvent limitation. Thus, both sets of claims cover the same product, i.e. any paroxetine hydrochloride when made by conversion of paroxetine methanesulfonate.

Secondly, the Examiner asserts that the claimed use of ethyl acetate will produce paroxetine hydrochloride anhydrate as per the teachings in Ward >132. But claim 29, which depends from claim 26, does **not** recite a particular solvent for the mesylate to hydrochloride salt conversion. Instead, claims 26 and 29 recite that the starting material, crystalline paroxetine methanesulfonate, was prepared by crystallization from ethyl acetate. Thus, claim 26 deals with further specifying the starting material paroxetine

methanesulfonate, and not with the salt conversion conditions as the Examiner proposes. Likewise, claim 29 is not limited to a paroxetine hydrochloride anhydrate in as much as it is not limited to forming paroxetine hydrochloride in ethyl acetate, and the Examiner's attempted distinction between Craig and Ward' 132 is erroneous. The instant claims 27-29 cover the same products as claimed in claims 2 and 4 of the issued Craig patent.

Thirdly, the Examiner indicates that interference should not be declared because the claims are not allowable. But, claim 26 has been indicated by the Examiner as containing allowable subject matter. Pursuant to MPEP '2307.02, one allowable claim is sufficient for the case to go to interference. The fact that not all the claims are deemed allowable should not prevent a declaration of interference.

Should the Examiner maintain this rejection despite the fact that the instant claims are not distinguishable from the claimed subject matter of Craig, it is requested that the Director of TC 1600 review and approve the Examiner's position as required by MPEP '2307.02. That is, a rejection of the instant claims 27-29 is an "admission" by the USPTO that an issued claim (Craig claims 2 and 4) is not patentable and such action requires approval from the TC Director according to the MPEP. A declaration of interference is again requested.

REJECTION UNDER '103

Claims 24 and 25 have been rejected under 35 U.S.C. '103(a) as allegedly being unpatentable over Stemp et al. (EP 190,496) in view of Barnes et al. (U.S. 4,721,723). This rejection is respectfully traversed.

The Examiner has failed to establish a *prima facie* case of obviousness. Stemp fails to generically disclose the presently claimed starting material, namely paroxetine methanesulfonate. The various pharmaceutically acceptable salts set forth on page 3 of Stemp et al. refer to compounds of formula I, which compounds do not include paroxetine. The Examiner's reliance on page 3 is thus incapable of suggesting the applicants' claimed method.

Moreover, selecting paroxetine methanesulfonate from the genus of paroxetine salts has already been established to have been nonobvious by virtue of the Examiner's allowance of the grand-parent application, now 5,874,447. Given that it was unobvious for the skilled worker to select paroxetine methanesulfonate, it necessarily follows that it was further unobvious to select paroxetine methanesulfonate and use it in a reaction step as per present claims 24 and 25. See *In re Ochiai*, 37 USPQ2d 1127 (Fed. Cir. 1995)(all limitations must be considered in determining obviousness, including the specified starting material).

Barnes fails to overcome any of these shortcomings and is totally silent regarding even the possibility of a methanesulfonate salt.

Given that Stemp fails to teach or suggest the applicants' claimed salt conversion reaction and fails to teach or suggest selecting the applicants' specifically claimed starting material, the formation of the presently claimed subject matter could not have been obvious. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

CONCLUSION

In view of the remarks, reconsideration of the rejections and allowance of the application and/or declaration of interference are respectfully requested.

Should the Examiner have any questions, regarding this application, she is encouraged to contact applicants' undersigned representative at 703 502 9440.

Please charge any shortage in fees due in connection with the filing of this, concurrent and future replies, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Respectfully submitted,
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